APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/893,535	06/29/2001	Robert E. Arbogast	OHI 1717-008A	4457

8698 7590 09/24/2007	EXAMINER	
STANDLEY LAW GROUP LLP	COBANOGLU, DILEK B	
495 METRO PLACE SOUTH		
SUITE 210	ART UNIT	PAPER NUMBER
DUBLIN, OH 43017	3626	

MAIL DATE	DELIVERY MODE
09/24/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

PTOL-90A (Rev. 04/07)

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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Application Number: 09/893,535
Filing Date: June 29, 2001
Appellant(s): ARBOGAST ET AL.

MAILED

SEP 2 4 2007

GROUP 3600

Eric M. Gayan
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 06/18/2007 appealing from the Office action

mailed 08/08/2006.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial

proceedings, which will directly affect or be directly affected by or have a bearing on the

Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection

contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is

correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

6,463,351	CLYNCH	10-2002
6,581,204 B1	DeBUSK	6-2003

2002/0099631 A1   VANKER   7-2002

2001/0051787 A1   HALLER   12-2001

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that

form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 31-37, 39, 46-48, 65-67 and 82 are rejected under 35 U.S.C. 102(e) as

being unpatentable by Clynch (U.S. Patent No. 6,463,351 B1).

As per claim 31, Clynch discloses a method of configuring a medical device,

comprising the steps of:

      i.   populating a digital repository with information corresponding to a

plurality of medical device components (Clynch; col.4, lines 49-53 and

col.7, line 61 to col.18, line10);

      ii.   interviewing a patient having a need for a medical device to

determine at lest one patient attribute (Clynch; col.5, lines 1-6);

      iii.   storing the at least one patient attribute in a memory (Clynch; col.6, lines 36-40 and col. 9, lines 7-12); and

      iv.   querying the digital repository for a subset of medical device components based on the at least one patient attribute, the subset of medical device components collectively forming a medical device meeting the need of the patient (Clynch; col.7, lines 22-44 and 61-65 and col. 4, lines 14-39).

As per claim 32, Clynch discloses the method of claim 31, wherein the medical device comprises at least one of a lower extremity prosthetic device, an upper extremity prosthetic device, a lower extremity orthotic device, an upper extremity orthotic device, and a spinal orthotic device (Clynch; col.5, lines 4-6).

As per claim 33, Clynch discloses the method of claim 31, further comprising the step of: customizing at least one of the subset of medical device components to create a customized medical device further meeting the need of the patient (Clynch; col.7, lines 28-44).

As per claim 34, Clynch discloses the method of claim 31, wherein the querying step comprises:

      i.   querying the digital repository for a plurality of subsets of medical device components based on the at least one patient attribute, the subset of medical device components corresponding to a medical device meeting the need of the patient (Clynch; col.7, lines 22-44 and 61-65); and

ii.   ranking the plurality of subsets based on a ranking criteria (Clynch;

col.7, lines 28-34).

As per claim 35, Clynch discloses the method of claim 34, wherein the ranking

criteria is at least one of a weight of the medical device, a height of the medical device,

a width of the medical device, a cost of the medical device, an activity level supported

by the medical device, and an inventory status of the medical device (Clynch; col.7,

lines 34-44).

As per claim 36, Clynch discloses the method of claim 34, further comprising the

step of:

i.   selecting one of the plurality of subsets (Clynch; col.7, lines 63-65);

ii.   customizing the one of the plurality of subsets to create a

customized medical device further meeting the need of the patient

(Clynch; col.7, line 65 to col.8, line 10); and

iii.   ordering the customized medical device (Clynch; col.3, lines 19-24).

As per claim 37, Clynch discloses the method of claim 36, wherein the ordering

step comprises reviewing the customized medical device prior to ordering (Clynch;

col.3, lines 12-14).

As per claim 39, Clynch discloses the method of claim 31, wherein the

interviewing step comprises entering the at least one patient attribute via at least one of

a personal data assistant, a digitizer, a digital camera, and a digital video camera

(Clynch; col.6, lines 50-54 and col.9, lines 7-12).

As per claim 46, Clynch discloses a system for configuring a medical device, comprising:

        i.   means for populating a digital repository with information corresponding to a plurality of individual medical device components (Clynch; col.4, lines 49-53 and col.7, lines 61-63 and col. 4, lines 14-39);

        ii.   means for interviewing a patient having a need for a medical device to determine at least one patient attribute (Clynch; col.5, lines 1-6);

        iii.   means for storing the at least one patient attribute in a memory (Clynch; col.6, lines 36-40 and 50-54); and

        iv.   means for querying the digital repository for a subset of medical device components based on the at least one patient attribute, the subset of medical device components collectively forming a medical device meeting the need of the patient (Clynch; col.7, lines 22-44 and 61-65 and col. 4, lines 14-39).

As per claim 47, Clynch discloses the system of claim 46, wherein the medical device comprises at least one of a lower extremity prosthetic device, an upper extremity prosthetic device, a lower extremity orthotic device, an upper extremity orthotic device, and a spinal orthotic device (Clynch; col.5, lines 4-6).

As per claim 48, Clynch discloses the system of claim 46, further comprising: means for customizing at least one of the subset of medical device components to create a customized medical device further meeting the need of the patient (Clynch; col.7, lines 28-44).

As per claim 65, Clynch discloses a method for configuring a medical device,

comprising the steps of:

    i.   populating a digital repository with information corresponding to a

plurality of individual medical device components (Clynch; col.4, lines 49-

53 and co1.7, lines 61-63 and col. 4, lines 14-39);

    ii.   populating the digital repository with patient historical information

associated with a patient (Clynch; col.9, lines 7-12);

    iii.   interviewing the patient having a need for a medical device to

determine at least one patient attribute (Clynch; col.5, lines 1-6);

    iv.   storing the at least one patient attribute in a memory via a digital

communication link (Clynch; col.6, lines 36-43);

    v.   querying the digital repository for a subset of medical device

components based on the at least one patient attribute, the subset of

medical device components collectively forming a medical device meeting

the need of the patient (Clynch; co1.7, lines 22-44 and 61-65 and col. 4,

lines 14-39);

    vi.   ordering the medical device over the digital communication link

(Clynch; col.3, lines 12-14); and

    vii.   storing information corresponding to the medical device in the

digital repository associated with the patient (Clynch; col.6, lines 36-40

and col. 9, lines 7-12).

As per claim 66, Clynch discloses the method of claim 65, wherein the medical device comprises at least one of a lower extremity prosthetic device, an upper extremity prosthetic device, a lower extremity orthotic device, an upper extremity orthotic device, and a spinal orthotic device (Clynch; col.5, lines 4-6).

As per claim 67, Clynch discloses the method of claim 65, wherein the patient historical information comprises at least one of reimbursement information and L code information (Clynch; col.9, lines 7-12).

> Examiner considers that this information includes L-code information for patients; which is described in applicant's specification as generating letters of necessity for patients, and for querying the practitioner local database or the central database for patient-specific information.

As per claim 82, Clynch discloses the method of claim 31, further comprising the steps of:

> i. customizing at least one of the subset of medical device components to create a customized medical device further meeting the need of the patient (Clynch; col.7, lines 22-44 and 61-65);
>
> ii. storing a customization result of the customizing step in the digital repository (Clynch; col.7, lines 22-44 and 61-65);
>
> iii. comparing the customization result to the subset of medical device components to identify a customization trend (Clynch; col.7, lines 28-44 and 61-63); and

iv.   adjusting an algorithm used in the querying step based on the

customization trend causing a different subset of medical device

components to be queried based on the at least one patient attribute

(Clynch; col.7, lines 28-44 and 61-63).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set
> forth in section 102 of this title, if the differences between the subject matter sought to be patented and
> the prior art are such that the subject matter as a whole would have been obvious at the time the
> invention was made to a person having ordinary skill in the art to which said subject matter pertains.
> Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5, 8-14, 16, 19, 20, 22-30 and 80-81are rejected under 35 U.S.C.

103(a) as being unpatentable over Clynch (U.S. Patent No. 6,463,351 B1) in view of

DeBusk et al. (U.S. Patent No. 6,581,204 B1).

As per claim 1, Clynch discloses a system for configuring a medical device,

comprising:

i.   a digital repository populated with entries defining a plurality of

medical device components, each entry associated with an individual

medical device component and having at least one patient attribute

indicator (Clynch; col. 4, lines 49-53 and col. 7, line 61 to col. 8, line 10);

ii.   a processor (Clynch; col.3 ,lines 12-19); and

iii.   a computer readable medium encoded with processor readable

instructions that when executed by the processor implement (Clynch;

col.3, lines 39-53)

iv.   a practitioner user interface mechanism configured to provide a

practitioner with access to entries in the digital repository via a network

and to allow the practitioner to provide at least one patient interview

answer indicator (Clynch; col.5 ,lines 1-6. and col. 6, lines 40-43),

v.   a patient interview mechanism configured to receive over the

network the at least one patient interview answer indicator corresponding

to an attribute of a patient and to store the at least one patient interview

answer indicator in a memory (Clynch; col.5 ,lines 1-6), and a

vi.   configurator mechanism configured to select a subset of entries

from the digital repository based on the at least one patient interview

answer indicator in the memory, the subset of entries including entries

corresponding to individual medical device components that collectively

form a medical device meeting a need of the patient (Clynch; col.7 ,lines

22-44 and 61-65).

>Clynch fails to expressly teach the individual medical device having
>
>component identification indicator and component class indicator,
>
>per se, since it appears that Clynch is more directed to storing
>
>default modifications in the database and when the modification is
>
>selected, the shape and location of the modification is displayed on
>
>the image and updated on the pull down modification menu.
>
>However, this feature is well known in the art, as evidenced by
>
>DeBusk et al.

In particular, DeBusk et al. discloses a modular tracking and profiling system wherein individual medical device component having component identification indicator (DeBusk et al, item 114) and component class indicator (DeBusk et al, item 112)(see DeBusk et al; col.17, line 56 to col.18, line 17).

It would have been obvious to one having ordinary skill in the art at the time of the invention to have combined the storing default modifications in the database and when the modification is selected, the shape and location of the modification is displayed on the image and updated on the pull down modification menu with the individual medical device having component identification indicator and component class indicator with the motivation of minimizing inventory and labor costs (DeBusk et al; col. 17, lines 26-34).

As per claim 2, Clynch discloses the system of claim 1, wherein the medical device comprises at least one of a lower extremity prosthetic device, an upper extremity prosthetic device, a lower extremity orthotic device, an upper extremity orthotic device, and a spinal orthotic device (Clynch; col.5, lines 4-6).

As per claim 3, Clynch discloses the system of claim 1, wherein:

  i.   the computer readable medium is further encoded with processor readable instructions that when executed by the processor further implement (Clynch; col.3, lines 39-43)

ii.   a customization mechanism configured to at least one of add,

remove, and modify at least one entry of the subset of entries selected by

the configurator mechanism, and the practitioner user interface

mechanism is further configured to provide access to the customization

mechanism (Clynch; col.7, lines 22-44 and 61-65).

As per claim 4, Clynch discloses the system of claim 3, wherein the practitioner

user interface mechanism is further configured to provide a summary page of

components customized by the customization mechanism (Clynch; col.6, lines 5-15).

As per claim 5, Clynch discloses the system of claim 1, wherein:

i.   the computer readable medium is further encoded with processor

readable instructions that when executed by the processor further

implement (Clynch; col.3, lines 39-43)

ii.   a medical device shopping mechanism configured to place an order

for the medical device and to store order information in the digital

repository, and the practitioner user interface mechanism is further

configured to provide access to the medical device shopping mechanism

(Clynch; col.5, line 53 to col. 6, line 17).

As per claim 8, Clynch discloses the system of claim 1, wherein at least a portion

of the network comprises an Internet protocol based network (Clynch; col.37, lines 48-

53).

As per claim 9, Clynch discloses the system of claim 1, wherein a least a portion

of the network is the Internet (Clynch; col.37, lines 48-53).

As per claim 10, Clynch discloses the system of claim 1, wherein the digital

repository comprises:

       i.   a central digital repository (Clynch; col.7, lines 61-63 and col. 1, line

      66 to col. 2, line 28), and

       ii.   a practitioner local digital repository remote from the central

      database (Clynch; col.3, lines 12-24 and Fig. 2).

As per claim 11, Clynch discloses the system of claim 10, wherein: at least one

of the practitioner local digital repository and the central digital repository is further

populated with patient historical entries, the patient historical entries each associated ·

with an individual patient and having a patient identification indicator, and at least one

patient history indicator (Clynch; col.9, lines 7-12).

            Examiner considers that since the patient has access to the local

            physician's office, the patient should have an identification indicator

            and history indicator.

As per claim 12, Clynch discloses the system of claim 11, wherein the at least

one patient history indicator comprises information corresponding to a medical device of

the individual patient (Clynch; col.9, lines 7-12 and col. 5, lines 1-4).

As per claim 13, Clynch discloses the system of claim 12, and

            The obviousness of modifying the teaching of Clynch to include the

            medical device of an individual patient comprises an identification number

            (as taught by DeBusk et al) is as addressed above in the rejection of claim

            1 and incorporated herein (DeBusk et al; col. 17, lines 26-34).

As per claim 14, Clynch discloses the system of claim 11, wherein: the patient historical entries further have at least one patient care indicator (Clynch; col.9, lines 7-12 and col. 5, lines 1-4).

As per claim 16, Clynch discloses the system of claim 15, wherein the reimbursement information comprises an L code indicator (Clynch; col.9, lines 7-12).

Examiner considers that this information includes L-code information for patients; which is described in applicant's specification as generating letters of necessity for patients, and for querying the practitioner local database or the central database for patient-specific information.

As per claim 19, Clynch discloses the system of claim 1, wherein:

i.   the computer readable medium is further encoded with processor readable instructions that when executed by the processor further implement (Clynch; col.3, lines 12-19)

ii.   a patient letter of necessity generation mechanism configured to generate a letter of necessity for the patient based on information stored in the digital repository and to store the letter of necessity in the digital repository (Clynch; col.6, lines 5-15), and

iii.   the practitioner user interface mechanism is further configured to provide access to the patient letter of necessity generation mechanism (Clynch; col.9, lines 7-12).

As per claim 20, Clynch discloses the system of claim 1, wherein the digital repository comprises a database (Clynch; col.7, lines 61-63).

As per claim 22, Clynch discloses the system of claim 21, wherein the external device is at least one of a digitizer, a digital camera, and a digital video camera (Clynch; col.6, lines 50-54 and col.9, lines 7-12).

As per claim 23, Clynch discloses the system of claim 1, wherein:

    i.   the entries in the digital repository further have a ranking indicator (Clynch; col.7, lines 28-34), and

    ii.   the configurator mechanism is further configured to select a plurality of subsets of entries from the digital repository based on the at least one patient interview answer indicator in the memory, each of the plurality of subsets including entries corresponding to individual medical device components of a medical device meeting the need of the patient and being ranked based on the ranking indicator of the entries (Clynch; col.7, lines 22-44 and 61-65).

As per claim 24, Clynch discloses the system of claim 23, wherein the ranking indicator comprises at least one of a component cost indicator, a component weight indicator, a component height indicator, a component width indicator, a component activity level indicator, and an inventory indicator (Clynch; col.7, lines 34-44).

As per claim 25, Clynch discloses the system of claim 23, wherein:

    i.   the computer readable medium is further encoded with processor readable instructions that when executed by the processor further implement (Clynch; col.3, lines 39-53)

      ii.   a customization mechanism configured to select one of the plurality

of subsets of entries and at least one of add, remove, and modify at least

one entry of the one of the plurality of subsets of entries selected by the

configurator mechanism (Clynch; col.5, lines 53-67), and

      iii.   the practitioner user interface mechanism is further configured to

provide access to the customization mechanism (Clynch; col.5, lines 53-

67).

As per claim 26, Clynch discloses the system of claim 25, wherein:

      i.   the computer readable medium is further encoded with processor

readable instructions that when executed by the processor further

implement (Clynch; col.3, lines 39-53)

      ii.   a medical device shopping mechanism configured to place an order

for the medical device corresponding to the one of the plurality of subsets

of entries selected by the customization mechanism and to store order

information in the digital repository, and the practitioner user interface

mechanism is further configured to provide access to the medical device

shopping mechanism (Clynch; col.5, line 53 tocol.6, line 17).

As per claim 27, Clynch discloses the system of claim 25, wherein the

practitioner user interface mechanism is further configured to provide a summary page

of components customized by the customization mechanism (Clynch; col.6, lines 5-15).

As per claim 28, Clynch discloses the system of claim 1, wherein:

    i.   the computer readable medium is further encoded with processor

readable instructions that when executed by the processor further

implement (Clynch; col.3, lines 39-43)

    ii.   a catalog mechanism configured to select a subset of entries from

the digital repository based on a query and to provide the subset of entries

to the practitioner user interface mechanism (Clynch; col.7, lines 22-44

and 61-65), and

    iii.   a medical device component shopping mechanism is configured to

place an order for a medical device component corresponding to at least

one selected entry of the subset of entries and to store order information

in the digital repository (Clynch; col.5, line 53 to col. 6, line 17)

    iv.   the practitioner user interface mechanism is further configured to

accept the query from a user, to provide the query to the catalog

mechanism, and to select the at least one selected entry of the subset of

entries provided by the catalog mechanism (Clynch; col.5, line 53 to col. 6,

line 17).

As per claim 29, Clynch discloses the system of claim 28, wherein:

    i.   the computer readable medium is further encoded with processor

readable instructions that when executed by the processor further

implement (Clynch; col.3, lines 39-43)

    ii.   a customization mechanism configured to select at least one of the

subsets of entries and at least one of add, remove, and modify at least

one entry of the one of the plurality of subsets of entries selected by the

catalog mechanism, and the practitioner user interface mechanism is

further configured to provide access to the customization mechanism

(Clynch; col.5, line 53 to col. 6, line 17).

As per claim 30, Clynch discloses the system of claim 29, wherein the

practitioner user interface mechanism is further configured to provide a summary page

of components customized by the customization mechanism (Clynch; col.6, lines 5-15).

As per claim 80, Clynch discloses the system of claim 3, wherein:

i.   the customization mechanism is further configured to store a

customization result in the digital repository indicating a change made to

the subset of entries selected by the configurator mechanism (Clynch;

col.7, lines 22-44 and lines 61-65)., and

ii.   the computer readable medium is further encoded with processor

readable instructions that when executed by the processor further

implements (Clynch; col.3, lines 39-43).

iii.   an algorithm adjustment mechanism configured to adjust an

algorithm of the configurator mechanism based on the customization

result stored in the digital repository, the adjustment causing the

configurator mechanism to select a different subset of entries based on

the at least one patient interview answer indicator (Clynch; col.7, lines 28-

44).

As per claim 81, Clynch discloses the system of claim 80, wherein the algorithm adjustment mechanism comprises an application of artificial intelligence (Clynch; col.7, lines 28-44).

Claims 38, 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clynch (U.S. Patent No. 6,463,351 B1) in view of Vanker et al. (U.S. Patent Publication No. 2002/0099631 A1).

As per claim 38, Clynch discloses the method of claim 36.

Clynch fails to expressly teach the determining all applicable price discounts for the medical device for the practitioner, per se, since it appears that Clynch is more directed to provide a method for producing medical devices such as prosthetic, orthotic and precision fit devices. However, this feature is well known in the art, as evidenced by Vanker et al.

In particular, Vanker et al. discloses determining all applicable price discounts for the medical device for the practitioner (Vanker et al., paragraph 0025).

It would have been obvious to one having ordinary skill in the art at the time of the invention to have combined the method for producing medical devices such as prosthetic, orthotic and precision fit devices with determining all applicable price discounts for the medical device for the practitioner with the motivation of having a detailed usage and sale records component enables the

buyers to use a communications interface (Vanker et al., paragraph

0136).

As per claim 49, Clynch discloses the method of claim 46.

The obviousness of modifying the teaching of Clynch to include

determining all applicable price discounts for the medical device for the

practitioner (as taught by Vanker et al) is as addressed above in the

rejection of claim 38 and incorporated herein (Vanker et al., paragraph

0136).

Claims 68, 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over

Clynch (U.S. Patent No. 6,463,351 B1) in view of Haller et al. (U.S. Patent Publication

No. 2001/0051787 A1).

As per claim 68, Clynch discloses the method of claim 65.

Clynch fails to expressly teach sharing information in the digital

repository with an external system, per se, since it appears that

Clynch is more directed to provide a method for producing medical

devices such as prosthetic, orthotic and precision fit devices which

most of the modification of the digital image can be accomplished in

a local physician's office that the patient has already access.

However, this feature is well known in the art, as evidenced by

Haller et al.

In particular, Haller et al. discloses sharing information in the digital

repository with an external system (Haller et al., paragraph 0177).

It would have been obvious to one having ordinary skill in the art at

the time of the invention to have combined the method for

producing medical devices such as prosthetic, orthotic and

precision fit devices which most of the modification of the digital

image can be accomplished in a local physician's office that the

patient has already access with sharing information in the digital

repository with an external system with the motivation of patient,

health care provider or insurer confirm acceptance of charges for

updates or changes before or at the same time as they are

implemented (Haller et al.; paragraph 0177).

As per claim 69, Clynch discloses the method of claim 68.

Clynch fails to expressly teach the external system comprises at

least one of a patient management system, a billing system, and an

insurance reimbursement system, per se, since it appears that

Clynch is more directed to provide a method for producing medical

devices such as prosthetic, orthotic and precision fit devices which

most of the modification of the digital image can be accomplished in

a local physician's office that the patient has already access.

However, this feature is well known in the art, as evidenced by

Haller et al.

In particular, Haller et al. discloses the external system comprises

at least one of a patient management system, a billing system, and

an insurance reimbursement system (Haller et al., paragraph

0177).

It would have been obvious to one having ordinary skill in the art at

the time of the invention to have combined the method for

producing medical devices such as prosthetic, orthotic and

precision fit devices which most of the modification of the digital

image can be accomplished in a local physician's office that the

patient has already access with the external system comprises at

least one of a patient management system, a billing system, and an

insurance reimbursement system with the motivation of patient,

health care provider or insurer confirm acceptance of charges for

updates or changes before or at the same time as they are

implemented (Haller et al.; paragraph 0177).

Claims 6, 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over

Clynch (U.S. Patent No. 6,463,351 B1) and DeBusk et al. (U.S. Patent No. 6,581,204

B1) as described above for rejection of claim 1, in further view of Vanker et al. (U.S.

Patent Publication No. 2002/0099631 A1).

As per claim 6, Clynch discloses the method of claim 5.

The obviousness of modifying the teaching of Clynch to include

determining all applicable price discounts for the medical device for the

practitioner (as taught by Vanker et al) is as addressed above in the

rejection of claim 38 and incorporated herein (Vanker et al., paragraph

0136).

As per claim 7, Clynch discloses the method of claim 1.

> Clynch fails to expressly teach at least a portion of the practitioner
>
> user interface mechanism is accessible via a personal data
>
> assistant, per se, since it appears that Clynch is more directed to
>
> any personal computer system commonly available in most
>
> physician's clinics (Clynch; col. 7, lines 17-22). However, this
>
> feature is well known in the art, as evidenced by Vanker et al.
>
> In particular, Vanker et al. discloses practitioner user interface
>
> mechanism is accessible via a personal data assistant (Vanker et
>
> al., paragraph 0042).
>
> It would have been obvious to one having ordinary skill in the art at
>
> the time of the invention to have combined the method for
>
> producing medical devices such as prosthetic, orthotic and
>
> precision fit devices which most of the modification of the digital
>
> image can be accomplished in a local physician's office that the
>
> patient has already access with the practitioner user interface
>
> mechanism is accessible via a personal data assistant with the
>
> motivation of communication with the central independent
>
> repository without need for a specific and proprietary
>
> communications protocol (Vanker et al.; paragraph 0042).

Claims 15, 17, 18 and 21 are rejected under 35 U.S.C. 103(a) as being

unpatentable over Clynch (U.S. Patent No. 6,463,351 B1) and DeBusk et al. (U.S.

Patent No. 6,581,204 B1) as described above for rejection of claim 1, in further view of

Hailer et al. (U.S. Patent Publication No. 200210099631 A1).

As per claim 15, Clynch discloses the system of claim 14.

> Clynch fails to expressly teach the patient care indicator comprises
>
> reimbursement information, per se, since it appears that Clynch is
>
> more directed to provide a method for producing medical devices
>
> such as prosthetic, orthotic and precision fit devices which most of
>
> the modification of the digital image can be accomplished in a local
>
> physician's office that the patient has already access. However, this
>
> feature is well known in the art, as evidenced by Haller et al.
>
> In particular, Haller et al. discloses the patient care indicator
>
> comprises reimbursement information. (Haller et al., paragraph
>
> 0177).
>
> It would have been obvious to one having ordinary skill in the art at
>
> the time of the invention to have combined the method for
>
> producing medical devices such as prosthetic, orthotic and
>
> precision fit devices which most of the modification of the digital
>
> image can be accomplished in a local physician's office that the
>
> patient has already access with patient care indicator comprises
>
> reimbursement information with the motivation of patient, health

care provider or insurer confirm acceptance of charges for updates

or changes before or at the same time as they are implemented

(Haller et al.; paragraph 0177).

As per claim 17, Clynch discloses the system of claim 11.

The obviousness of modifying the teaching of Clynch to include

interface with an external system (as taught by Haller et al) is as

addressed above in the rejection of claim 68 and incorporated

herein (Haller et al., paragraph 0177).

As per claim 18, Clynch discloses the system of claim 17.

The obviousness of modifying the teaching of Clynch to include the

external system comprises at least one of a patient management

system, a billing system, and an insurance reimbursement system

(as taught by Haller et al) is as addressed above in the rejection of

claim 69 and incorporated herein (Haller et al., paragraph 0177).

As per claim 21, Clynch discloses the system of claim 1.

The obviousness of modifying the teaching of Clynch to include

interface with an external system (as taught by Haller et al) is as

addressed above in the rejection of claim 68 and incorporated

herein (Haller et al., paragraph 0177).

(10) Response to Arguments

In the Appeal Brief filed 06/18/2007, Appellant makes the following arguments:

A. Clynch does not teach interviewing a patient.

B. Clynch does not teach querying a digital repository of medical device

components.

Examiner will address Appellant's arguments in sequence as they appear in the

brief.

Argument A:

In response to Appellant's first argument, the Examiner respectfully submits that

the method claim 31 recites: "interviewing a patient having a need for a medical

device to determine at least one patient attribute"; Clynch teaches "a method of

producing a medical device, such as a prosthetic or orthotic structure" in abstract,

"In accordance with the method, the process of constructing a medical device

begins in a physician's clinic 10 where in step 20, a modeling material is fitted to

the body part of a patient requiring a medical device. As described above, the

medical device may be a prosthetic, orthotic, radiological or any other

anthropometric precision fit device" in col. 5, lines 1-6. It is well known to one of

the ordinary skill in the art, at the time of the invention, that there has to be an

interaction between the patient and the physician, and physician would obtain at

least one patient attribute (such as patient's weight, height, size and shape of the

desired prosthetic medical device, or patient's activity level).

Argument B:

In response to Appellant's second argument, the Examiner respectfully submits

that Clynch teaches "The digitized scanned image 60 of the model is displayed in

a window on the left hand side of the monitor. The modeled image shown is that

of a below knee amputation, but any body portion may be imaged, including a

foot, knee, leg, hip, back, shoulder, torso, arm, hand, neck or head for example.

A pull down menu 62 is displayed in a window adjacent the scanned image. The

pull down menu 62 includes the default options for modifying the scanned image

to produce a mold to be used in the manufacture of the medical device or to

produce a medical device directly from the modified image. The list of default

modifications is available on a scrolling sub-menu 64. The options on the

scrolling sub-menu depend on the type of medical device to be produced.

Regardless of the type of device, a "uniform shrink" and a "smooth" option are

available to permit the image to be uniformly shrunk in order to compensate for

the thickness of the model and yield an accurately dimensioned image

representative of the body part for which the device is to be produced. The

smooth option converts the surface of the modified image into a smooth surface

having the appearance of the mold that will be produced from the machine code

generated from the modified image. Other options on the modification menu, as

noted above, are device dependent. For example, the options available for a

below knee prosthetic device include modifications for: Patellar Tenon Bar, Crest

of Tibia, Supracondylar Constriction, Anterior Prominence of Femoral Condyle,

Anterior Latter Tibial Prominence, Head of the Fibula Lateral Femoral Condyle,

Distal End of the Fibula, Adductot Tubercal, Distal End Extension, and Posterior

Wall Extension." in col. 7, lines 24-52 and in figure 3. Examiner respectfully

submits that these options of body parts may form a whole leg, therefore they

may be components of a complex medical device. Clynch continues in col. 7,

lines 53-65 that "The default modification set for a knee orthosis includes Crest of

Tibia, Anterior Lateral Tibial Prominence, Supracondylar Constriction, Medial

Anatomical Joint and Lateral Anatomical Joint. The default modification set for a

podiatric orthosis include modifications directed to correcting/relieving the effects

of plantar fasiitis or calcaneous heel spur, Metatarsalgia or Morton's Neuroma,

sesamoiditis and pescavus. Each of these default modifications are stored in a

database of imperically derived data based on prior successful medical devices.

When a default modification is selected, the shape and location of the

modification is displayed on the image and updated on the pull down modification

menu 62." And in col. 3, lines 12-24, Clynch teaches "the digital image to be

manipulated and modified with the assistance of a database of default

modifications", therefore Clynch teaches querying a digital repository (or

database) of medical device components.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the

Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Dilek B. Cobanoglu

DBC

September 12, 2007

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